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EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/789,433	MULDOON ET AL.	
	Examiner	Art Unit	
	Ja-Na Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *1-9 and 19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. The amendment filed April 24, 2007 has been entered. Claims 10 and 17 have been amended. Claims 1-9 and 19 have been withdrawn from consideration. Claims 10-18 and SEQ ID NO:2 are under consideration in this office action.

Withdrawal of Rejections

2. The following rejections have been withdrawn in view of applicants' amendments and arguments:

a) The written description rejection of claim 17 under 35 U.S.C. 112, first paragraph;

b) The rejection of claims 10-13 under 35 U.S.C. 102(b) as being anticipated by Takahashi et al. (Clin. Biochem. 1996. Vol. 29(4): 301-308); and

c) The rejection of claims 10, 11, 13, 17 and 18 under 35 U.S.C. 102(b) as being anticipated by Chen et al., (Meat Science. 2002. Vol. 61:55-60, available on online December 21, 2001).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 10-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Sheng et al (J. of Bio. Chem. 1992. Vol. 367(35): 25,407-25,413).

Claim 10 is drawn to an assay for detecting a mammalian troponin molecule in a sample, the assay comprising: a) reacting the sample with a ligand that is specific for the mammalian troponin molecule and not specific for an avian troponin molecule for a time and under conditions sufficient to form a complex between the ligand and the troponin molecule; and b) detecting the complex either directly or indirectly as a measure of the presence or amount of the troponin molecule in the sample and wherein the ligand reacts with or binds to an amino acid sequence selected from the group consisting of SEQ ID NO:2. Claim 11 is drawn to the mammalian troponin molecule is a troponin I molecule. Claim 12 is drawn to the mammalian troponin molecule is a troponin I molecule is selected from the group consisting of a slow twitch skeletal muscle troponin I molecule and a fast twitch skeletal muscle troponin I molecule. Claim 13 is drawn to the ligand being an antibody and the troponin molecule is a polypeptide. Claim 14 is drawn the ligand being an antibody produced by immunizing an animal with a peptide having an amino acid sequence selected from the group consisting of SEQ ID NO: 2. Claim 15 is drawn to the ligand binds to a peptide having an amino acid sequence selected from the group consisting of SEQ ID NO: 2. Claim 16 is drawn to the ligand binds to a nucleic acid molecule encoding a peptide having an amino acid sequence selected from the group consisting of SEQ ID NO: 2.

Sheng et al., teach assay for detecting a mammalian rabbit skeletal muscle the polypeptide or cDNA troponin I (TnI) molecule in a lysate sample, by western blotting whereby the sample contains a rabbit fast skeletal monoclonal antibody ligand specific for troponin I having SEQ ID NO:2 to form a complex between the antibody and troponin I; and detecting the complex as a measure of the presence of the troponin I (Figure 3). In Figure 3, Sheng et al., show an immunoblot result and detection of TnI with a monoclonal antibody. Sheng et al., teach affinity chromatography techniques where ligands such as troponin C or F-actin selectively bound TnI, and the TnI proteins were detected by UV or western blotting methods (page 25,408, col.2). Sheng et al., teach rabbit skeletal muscle cDNA clone for troponin I and encoding rabbit fast twitch skeletal muscle TnI (page 25, 408, col.1). Sheng et al., teach the cDNA and the deduced amino acid sequence of rabbit fast skeletal muscle TnI in Figure 1 and the nucleotide sequence homology of rabbit and mouse TnI in Figure 2. Sheng et al., teach monoclonal antibodies that react with or binds to SEQ ID NO:2. Furthermore Sheng et al., teach the production of the rabbit fast skeletal muscle TnI monoclonal antibody which inherently includes a monoclonal antibody produced by immunizing an animal with the peptide having SEQ ID NO:2 (page 25,409, col. 2). Sheng et al., also teach a ligand that binds to SEQ ID NO:2; and a ligand that binds to a nucleic acid molecule encoding a peptide having the amino acid sequence of SEQ ID NO:2.

Thus, Sheng et al., teach claims 10-16.

Response to Arguments

4. Applicant's arguments filed April 24, 2007 have been fully considered but they are not persuasive.

Applicants assert that residues 35, 39, 46, 47, 48, 53, 54, 56, 59 and 84 of Figure 1 in Sheng et al., are different. However, Sheng et al., references accession number L04347. L04347 is rabbit troponin I wherein the mRNA translation has amino acid 34, 38, 45-47, 52-53,56, 59 and 84 having identical amino acids as those shown at positions 35, 39, 46-48, 53-54,56,59 and 84 of SEQ ID NO:2. With respect to Figure 1, the rabbit troponin I wherein the mRNA translation has amino acid 34, 38, 45-47, 52-53,56, 59 and 84 as having identical amino acids as those shown at positions 35, 39, 46-48, 53-54,56,59 and 84 of SEQ ID NO:2. Therefore, Sheng et al., teach the amino acid sequence of SEQ ID NO:2. Furthermore, the rabbit fast skeletal monoclonal antibody ligand specific for troponin I ligand of Sheng et al., will react with or bind to SEQ ID NO:2 and the sequence of Figure 1 and the sequence of L04347. The GenCore sequence alignment also shows 100% sequence identity between SEQ ID NO:2 and the sequence of Sheng et al. It is noted that the troponin molecule of Claim 10 does not have to be SEQ ID NO:2, rather the claim requires that the ligand binds or react with SEQ ID NO:2. Because of the high sequence similarity of the troponin of Sheng et al., and SEQ ID NO:2, a ligand that binds the troponin of Sheng et al., will also bind SEQ ID NO:2.

New Grounds of Rejection Necessitated by Amendment

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 10-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al., (Meat Science. 2002. Vol. 61:55-60, available on online December 21, 2001) in view of Sheng et al (J. of Bio. Chem. 1992. Vol. 367(35): 25,407-25,413).

Claim 10 is drawn to an assay for detecting a mammalian troponin molecule in a sample, the assay comprising: a) reacting the sample with a ligand that is specific for the mammalian troponin molecule and not specific for an avian troponin molecule for a time and under conditions sufficient to form a complex between the ligand and the troponin molecule; and b) detecting the complex either directly or indirectly as a measure of the presence or amount of the troponin molecule in the sample and wherein the ligand reacts with or binds to an amino acid sequence selected from the group consisting of SEQ ID NO:2. Claim 11 is drawn to the mammalian troponin molecule is a troponin I molecule. Claim 12 is drawn to the mammalian troponin molecule is a troponin I molecule is selected from the group consisting of a slow twitch skeletal muscle troponin I molecule and a fast twitch skeletal muscle troponin I molecule. Claim 13 is drawn to the ligand being an antibody and the troponin molecule is a polypeptide. Claim 14 is drawn the ligand being an antibody produced by immunizing an animal with a peptide having an amino acid sequence selected from the group consisting of SEQ ID NO: 2. Claim 15 is drawn to the ligand binds to a peptide having an amino acid sequence selected from the group consisting of SEQ ID NO: 2. Claim 16 is drawn to

the ligand binds to a nucleic acid molecule encoding a peptide having an amino acid sequence selected from the group consisting of SEQ ID NO: 2. Claim 17 is drawn the ligand is specific for an equine troponin I protein, a porcine troponin I protein or a bovine troponin I protein. Claim 18 is drawn to the sample being animal feed.

Chen et al., teach immunological methods for detecting the porcine troponin I wherein immunoblotting was performed using isolated proteins detected by a monoclonal antibody (page 56, col.2). Chen et al., teach an indirect ELISA using the monoclonal antibody as the detection reagent for detecting porcine skeletal troponin I (sTnI) (page 57, col.1). Figure 2 shows the result of detecting porcine sTnI in a sample for a time and under conditions sufficient to form a complex between the ligand and the troponin; and indirectly detecting the complex as a measure of the presence or amount of the troponin molecule in the sample. Chen et al., teach the specificity of the monoclonal antibody which recognized porcine sTnI but not other troponin molecules from chicken (page 58, col.2). Chen et al., teach the production of monoclonal antibodies from immunized mice (page 56, col.2). The samples were raw and cooked porcine muscle extracts (page 56, col. 1-2). It is noted that the specification at page 5, lines 6-11 teach that the term "animal feed" refers to any substance provided to an animal for nourishment, including preparations from meat products from animals for human consumption. Therefore the use of raw and cooked porcine muscle samples, meets the limitation drawn to animal feed sample.

Chen et al., teach that several specific monoclonal antibodies have been raised to provide a consistent and continuous supply of immunoreagents for routine immunoassays for the detection of bovine, porcine and chicken adulteration in meat mixtures (page 55, col.1). Chen et al., teach it is important to reveal the identity and specific antigenicity of the skeletal muscle troponin from several other species for the

development of species-specific antibodies (page 55, col.2). Chen et al., teach the recognition and use of monoclonal antibodies as specific for sTnI and demonstrated the heterogeneity of sTnI is differentiated immunologically with antibodies at the species level (page 56, col.1). Chen et al., teach sTnI is an ideal species marker for immunoassays for the detection of species origins in the meats of severely heat-processed commodities (page 60, col.1).

However Chen et al., do not explicitly teach a ligand that reacts with or binds to SEQ ID NO:2.

Sheng et al., has been discussed above as teaching an assay for detecting a mammalian rabbit skeletal muscle troponin I (TnI) molecule in a sample, by western blotting and immunoblotting wherein the sample contains a rabbit fast skeletal monoclonal antibody ligand specific for troponin I having SEQ ID NO:2 to form a complex between the ligand -antibody and troponin I; and detecting the complex as a measure of the presence of the troponin I (Figure 3).

Therefore it would have been prima facie obvious at the time of applicants' invention to apply the ligand reacts with or binds to an amino acid sequence selected from the group consisting of SEQ ID NO:2 of Sheng et al, to Cheng et al., assay for detecting a mammalian troponin molecule in a sample in order to provide a consistent and continuous supply of immunoreagents for routine immunoassays for the detection of species adulteration in meat mixtures. One of ordinary skill in the art would have a reasonable expectation of success by exchanging the monoclonal antibody ligand of Cheng et al., for the ligand of Sheng et al., which reacts with or binds to an amino acid sequence selected from the group consisting of SEQ ID NO:2 because Cheng et al., teaches the desire to have specific troponin species marker for detection immunoassays. Furthermore, no more than routine skill would have been required to

include the ligand of Cheng et al., for the available ligand of Sheng et al., since Cheng et al., teach the desire to have a variety of mammalian troponin ligands such as the ligand of Sheng et al., that selectively bind SEQ ID NO:2 or rabbit troponin and have the ability to not be specific for avian troponin molecules. Finally it would have been prima facie obvious to combine the invention of Cheng et al., and Sheng et al., to advantageously achieve the detection of mammalian troponin in adulterated meat samples.

Conclusion

6. No claims allowed.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Jeffery Siew, can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines
July 2, 2007

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER